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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,786	03/19/2004	Sukhendu B. Dev	1180-con 3	7772

7590 11/30/2005

Daniel M. Chambers
Bio Technology Law Group
658 Marsolan Ave.
Solana Beach, CA 92075

EXAMINER	
GRAY, PHILLIP A	

ART UNIT	PAPER NUMBER
3767	

DATE MAILED: 11/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/804,786	DEV ET AL.	
	Examiner	Art Unit	
	Phillip Gray	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
The specification to which the oath or declaration is directed has not been adequately identified. See MPEP § 602.

The applicants' declaration references an application filed on June 24, 1996 not March 19, 2004.

Information Disclosure Statement

The information disclosure statement filed March 19, 2004 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because it fails to identify the current application. It references an application filed on December 14, 2001. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Claim Objections

Claim 8 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is

required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 8 recites the limitation "The method of claim wherein, wherein after the ..." in the first line of the claim. It is likely that Claim 8 is meant to be a dependant claim from Claim 7. Claim 8 is currently an indefinite independent claim; it fails to limit the invention, and creates antecedent basis problems in the claim. Appropriate correction is required on Claim 8.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Dev et al. (U.S. Patent Number 5,944,710). Dev patent 710' shows a method for electroporation mediated intravascular delivery as does this application. Dev patent 710' discloses a method useful for delivery of therapeutic compositions such as antithrombotic and anticoagulant agents. The specification and abstract disclosed in the Dev patent 710' is identical to the specification and abstract disclosed in this application. The Dev patent 710' discloses all elements claimed in the application; method for drug delivery to a body vessel with a balloon catheter, with electrodes generating an electrical impulse to effect electoporation or ionophoresis (see column 4 lines 5-40), at a specific voltage, waveform, duration, and number of pulses (see column

10 line 25-67), where the composition administered is an antithrombotic, antirestenoitic, antiplatelet, polynucleotide or polypeptide (see columns 4-5).

Claims 7-8, 14-15,18-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Leone et al. (U.S. Patent Number 5,505,700). Leone shows a method for the delivery of medicaments directly to treatment sites within the living body. Leone teaches this method using an electro-osmotic infusion catheter with a distal balloon portion, an internal electrode, and an integral electrode, that is positioned along the catheter at its distal portion which electrical circuit influences the path of travel of the medicament to the target area. (See paragraph at column 2 line 40). The Leone method discloses inflating that balloon portion to define a treatment location and or to treat diseased or injured areas (see paragraph at column 2 line 46). The Leone method discloses different ways in which the electrodes my influence the path of the medicaments to the body; through electroporation (see paragraph at column 7 line 39), iontophoresis (see paragraph at column 7 line 9) or other electro-osmotic means. Leone further discloses electrical impulses that are generated by the electrodes to deliver the composition to the body (see paragraph at column 4 line 49). The Leone method of administration of the composition may be at the same time or after the electrical impulse is applied (claims 1 and 2). While not expressly stated in Leone, it is implicit in the method that the when the electrical impulses are stopped the balloon is deflated and the electro-osmotic catheter is removed (see paragraph atcolumn 2 line 40). It is also implicit in the Leone method that the vessel being treated may be a blood vessel, lymph vessel, adventitial region, or medial region (see paragraph at column 4

line 19). The Leone method is directed to use with respect "to other vessels or internal body components" (see paragraph at column 4 line 25).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leone in view of Sibalis (U.S. Patent Number 5,088,977). Leone discloses the claimed invention except for the explicit disclosure of the composition selected from a group consisting of an antithrombotic, antirestenotic, antiplatelet, platelet receptor, mediator inhibitor growth factor, antibody, anti-inflammatory and antiproliferative. Sibalis teaches that it is known to use various cardiovascular vasodilators in the class of antithrombotic, antirestenotic, antiplatelet compositions such as Heparin and Warfarin (as set forth in

paragraph at column 8, line 52), which may serve as both blood vessel dilators and also act to reduce or eliminate blood coagulation. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method for delivery of medicaments as taught by Leone with cardiovascular vasodilators in the class of antithrombotic, antirestenotic, and antiplatelet compositions such as Heparin and Warfarin as taught by Sibalis, since such a modification would provide the method for delivery of medicaments with cardiovascular dilators (antithromcotic, antirestenotic, antiplatelet, ect) to reduce or eliminate blood coagulation.

Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leone in view of Crandell (U.S. Patent Number 5,304,120). Leone discloses the claimed invention except for the electrical impulse voltage between 50 volts to about 100 volts and the electrical impulse duration between 100 microseconds to 10 milliseconds. Crandell teaches that it is known to use an electrical impulse between 50 volts to 100 volts and with a duration of 100 microseconds to 100 milliseconds. This is set forth in column 4 line 6 (voltage) and column 4 line 34 (duration) to make possible the preferred insertion of drugs or genes into endothelial cells (see paragraph at column 3 line 34). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method for delivery of medicaments as taught by Leone with electrical impulse between 50 volts to 100 volts and with a duration of 100 microseconds to 100 milliseconds as taught by Crandell, since such a modification would provide the method for delivery of medicaments with electrical impulse between

50 volts to 100 volts and with a duration of 100 microseconds to 100 milliseconds to make possible the preferred insertion of drugs or genes into endothelial cells.

Claims 16 –17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leone in view of Crandell. Leone discloses the claimed invention except for the electrical pulse waveform and the number of pulses applied. Crandell teaches that it is known to use between one to one hundred pulses and their waveform may be an "exponentially decaying pulse, a square pulse, a unipolar oscillating pulse train or a bipolar oscillating pulse train" (as set forth in paragraph at column 4 line 29) in order to make the walls of the endothelial cells transiently permeable. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method for delivery of medicaments as taught by Leone with one to one hundred pulses whose waveforms may be an "exponentially decaying pulse, a square pulse, a unipolar oscillating pulse train or a bipolar oscillating pulse train" as taught by Crandell, since such a modification would provide the method for delivery of medicaments with one and one hundred pulses whose waveforms may be an "exponentially decaying pulse, a square pulse, a unipolar oscillating pulse train or a bipolar oscillating pulse train" in order to make the walls of the endothelial cells transiently permeable.

Claims 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leone in view of Crystal et al. (U.S. Patent Number 6,329,348). Leone discloses the claimed invention except for the composition being a polynucleotide, which encodes a polypeptide selected from the group consisting of vascular endothelial growth factor

(VEGF), endothelial specific mitogen, platelet derived growth factor, fibroblast growth factor, and interferon. Crystal teaches that it is known to use growth factors, modified peptides, ribozymes, polynucleotides and other substances that induce angiogenesis, as set forth in column 2 line 19, to aid in the formation of new blood vessels as well as the promotion of collateral blood vessel growth (see paragraph at column 2 line 9). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method for delivery of medicaments as taught by Leone with a composition made up of growth factors, modified peptides, ribozymes, polynucleotides and other substances that induce angiogenesis taught by Crystal, since such a modification would provide the method for delivery of medicaments with a composition being a polynucleotide, which encodes a polypeptide selected from the group consisting of vascular endothelial growth factor (VEGF), endothelial specific mitogen, platelet derived growth factor, fibroblast growth factor to aid in the formation of new blood vessels as well as the promotion of collateral blood vessel growth.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gray whose telephone number is (571) 272-7180. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

PAG

KEVIN C. SIRMONS
PRIMARY EXAMINER